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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/297,092	05/18/99	PAULISTA M	P564-9010

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EXAMINER
STROUP, C

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/297,092

Applicant(s)

PAULISTA ET AL.

Examiner

Carrie Stroup

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment Paper 10, filed 10/26/00, has been entered. Claims 14-27 are currently pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15-16 remain, and claims 14 and 17-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Applicant states in Paper 10, page 2, that the description of a protein function is an acceptable method of describing a genus, particularly in view of the relevant references listed on pages 1-3 of the specification. The description of the biological function of the protein, or DNA encoding such, is a method of describing a genus, but it is not in many cases sufficient. For example, the current claims read on all protein fragments of the TGF- β superfamily with bone or cartilage inducing ability (claim 15), and a portion of SEQ ID NO:1 with said activity, or any protein sequence in any vertebrate with said activity, or DNA encoding such, or a fusion protein comprising such (claim 16b&c). Thus, the claims read on an enormous number of protein and DNA sequences, while not telling the artisan what specific portions or fragments contain the cartilage and/or bone inducing function. And although the art may have

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disclosed TGF- β heterodimers and some fusion proteins with cartilage and/or bone inducing function, said disclosures represent only a small portion of all the sequences encompassed by claims 15 and 16. Claims 14 and 17-27 are rejected for the same reasons because the claims encompass the subject matter as discussed above.

3. Claims 14-27 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an implant material comprising a bioactive material composed of calcium phosphate and at least one cartilage-inducing and/or bone inducing protein or DNA encoding thereof of the TGF- superfamily and methods of making and using such, does not reasonably provide enablement for an implant material comprising a bioactive matrix material composed of calcium phosphate and at least one cartilage-inducing and/or bone inducing protein or DNA encoding thereof, such as a protein fragment of the TGF- β superfamily, a portion of a mature part of SEQ ID NO: 1, or a fusion protein containing a portion of the TGF- β superfamily, and the process of making and using such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant's arguments filed 10/26/00 have been fully considered but they are not persuasive.

As stated above the specification does not disclose which fragments or portions of protein or DNA sequences, or fusion proteins of the TGF- β superfamily which induce cartilage and/or bone growth in vivo, nor is such widely known in the art. Therefore, one of skill in the art would have had to practice undue experimentation to determine which sequences from a TGF- β superfamily would meet this functional limitation.

4. Claims 14-15 and 17-27 remain rejected under 35 USC 103 as being obvious over Urist et al. in view of Opperman et al. and Yan et al.

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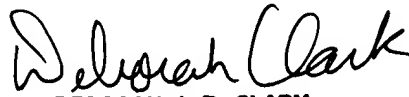
Applicants argue that Urist nor Opperman disclose a bioactive matrix as required by the present claims. However, Urist does disclose using a calcium phosphate and in view of Yan et al. one of skill in the art would be motivated to use a bioactive calcium phosphate to achieve further bone-inducing capabilities. Applicants argue that they cannot find a suggestion in the applied references to provide motivation to combine MP52 with a matrix having a bone inducing activity. However, only claim 16 provides such limitation. None of the other claims limit the DNA to DNA encoding MP52. Therefore, claims 14, 15, and 17-27 remain rejected for reasons of record.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Stroup whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached at (703) 305-4051. The fax phone number for this Group is (703) 308-0294.

Carrie Stroup


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